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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,250

10/17/2005

Hiroshi Kase

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09/09/2009

FITZPATRICK CELLA HARPER & SCINTO

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

09/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,250	<b>Applicant(s)</b> KASE ET AL.	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23, 25, 71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 71-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/6/2009 has been entered.

### ***Response to Arguments***

Applicant have presented arguments over the 35 USC 103 rejection that the Goodman & Gilman reference does not teach or address treatment of generalized anxiety disorder and that Goodman & Gilman's teaches only specific antidepressants for specific types of anxiety.

In response to the above arguments, it is once again noted that Goodman & Gilman's specifically states that antidepressants are leading choices in the treatment of severe anxiety disorders including generalized anxiety disorder in addition to other types of anxiety disorders. Goodman & Gilman's highlights a few specific types of anxiety that are treatable by certain antidepressants but this does not undermine the teachings of Goodman & Gilman's that antidepressants are the leading choice in the treatment of anxiety.

Due to Applicants amendments to the claims, please see the new grounds of rejection below.

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 and 71-72 rejected under 35 U.S.C. 103(a) as being unpatentable over Greenlee et al. (US PgPub 2003/0139395) in view of Suzuki et al. (US Patent 5,543,415) and Goodman & Gilman's: The Pharmacological Basis for Therapeutics, Tenth Edition, 2001, page 469.

Greenlee et al. teach that compounds with adenosine A<sub>2a</sub> receptor antagonist activity are useful in treating anxiety-related disorders in combination with antidepressants or anxiolytic agents (paragraph 0008). Examples of anxiety-related disorders include generalized anxiety disorder (paragraph 0008). Common anxiolytic agents that can be administered with the adenosine A<sub>2a</sub> receptor antagonist are listed in paragraph 0198 and include agents that do not have action at the adenosine A<sub>2a</sub> receptor.

Greenlee does not teach (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine as the adenosine A<sub>2a</sub> receptor antagonist.

Suzuki et al. teach antidepressant compositions containing a xanthine derivative or a pharmaceutically acceptable salt thereof, with the xanthine derivative being represented by Formula I (Col. 2, lines 1-41). In particular, Compound 74 overlaps with present claims 21 and 23 (see Table 1 and Reference Example 71). Test Example 1

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shows the effectiveness of the compounds of Formula I (including Compound 74) in an animal model of depression. The xanthine derivatives are known for their adenosine antagonistic action (Col.1, lines 29-49).

Goodman & Gilman's teaches that antidepressants are leading choices in the treatment of severe anxiety disorders, including generalized anxiety disorder, social phobia and obsessive-compulsive disorder and including the common comorbidity of anxiety in depressive illness (page 469).

Accordingly, one would be motivated to combine the teachings of Greenlee et al. which teach the treatment of anxiety disorders, such as generalized anxiety disorder, with adenosine  $A_{2a}$  receptor antagonists with Suzuki et al., which teach that compounds such as (E)-3-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) are antidepressants and the teachings of Goodman & Gilman's which teach that antidepressants are the leading choice in the treatment of severe anxiety disorders. Because Greenlee teaches that adenosine  $A_{2a}$  receptor antagonists are an effective treatment option for anxiety and Suzuki teaches that (E)-3-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) is a  $A_{2a}$  receptor antagonist that is an antidepressant and Goodman & Gilman's teaches that antidepressants are the leading choice for treating severe anxiety, one would be motivated to use the (E)-3-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) which is known as an anti-depressant, to treat anxiety.

### ***Conclusion***

No claims are allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617